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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

PASS, BARRY

ART UNIT PAPER NUMBER

3737

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,718

Applicant(s)

ERLACH ET AL.

Examiner

Barry Pass

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Drawings

1. The drawings are objected to because of the following minor informalities:
the feature "C" in Figure 1 is not disclosed in the *Specification*
in Figure 1 the nanochip, reference sign 30, is not clearly distinguished from the lead line and RBC border

the *Specification* discloses feature 24 for Figure 3, but the reference sign is not displayed in the drawing

Figure 3 shows reference signs 120 and 130 but these features are not disclosed in the *Specification*

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The *Specification* is objected to because of the following minor informalities:

In the middle paragraph on page 8 the NMR technique is disclosed as a means of monitoring electron dense nanoparticles. The appropriate technology would be electron spin resonance (ESR)

On page 9 the reference in the *Specification* to Table 1 contains a typographical error.

Claim Objections

3. Claim 5 is objected to because of the following informalities: “methodof” lacks proper spacing. Appropriate correction is required.

Double Patenting

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting, set forth in *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), as being unpatentable over claims 1-17 of copending Application No. 09727749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the broader claims of this application, which teach a nanodevice circulating in the body or located intra- or extracellularly, anticipate the more specific invention of a nanodevice to monitor a bodily condition disclosed in Application No. 09727749.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. Claims 3-14 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitations “the substrate” and “said cell” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 5, and 8 recite the limitation “said biological member” in line 1. Claim 7 recites this limitation in line 2. There is insufficient antecedent basis for this limitation in the claims.

Claims 3, 5, 6, 8, 9, 11, 14 and 16-19 are vague and indefinite in that they fail to positively set forth a further step in the method as set forth in claims 1 and 15.

Claim 10 is vague and indefinite in that it sets forth a limitation directed to a method of making rather than a method of using as set forth in claim 1.

Referring to claim 12 and 16, they are vague and indefinite as to how the device is to be “adapted for/to.”

Referring to claim 13, all the limitations disclosed lack any antecedent basis in claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 7 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Merkle.

Referring to claims 1, 2, 7 and 15 Merkle discloses in section 4, last paragraph, [nano]devices in the circulatory system that (section 5 second paragraph) circulate freely throughout the body and able to enter individual cells. These disclosures necessarily include

devices in any or all of the following milieus: blood vessels, interstitial spaces (extracellular) and intracellular.

Referring to claim 6, Merkle discloses in section 5 a [nano]device with a small computer able to determine the concentration of specific molecules, and able to receive broadcast instructions. These attributes necessarily include the limitations in the invention disclosed in claim 6.

Claim Rejections - 35 USC § 103

6. Claims 3-5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkle.

Merkle teaches a nanodevice entering a cell. Merkle does not teach methods of inserting into a cell. Referring to claim 4, in the absence of showing any criticality, the choice of a means of inserting into a cell would have been an obvious selection of known equivalents. Means such as electroporation are well known for use in creating openings in biological membranes.

Merkle teaches a nanodevice entering a cell. Merkle does not teach cell types. Referring to claims 3, 5 and 8, an individual of ordinary skill in the art at the time of invention would have recognized that the method of Merkle would be applicable to any cell type.

7. Claims 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkle in view of Peeters US Patent No. 6123819.

Merkle teaches a nanodevice circulating or stationed in the body but does not teach a substrate made of the usual semiconductor materials gallium arsenide, silicon, and silicon oxides. Peeters, in column 4 lines 14-18, teaches nanoelectrode arrays built on a semiconductor surface such as silicon. Referring to claim 9, it would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body could have a semiconductor substrate since the nanoelectrode arrays of Peeters is small enough in size to be incorporated into a nanodevice to provide active functions such as receiving and transmitting.

Peeters, in column 10 lines 32-33, teaches nanoelectrode arrays constructed on a semiconductor substrate by lithography. Referring to claim 10, it would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body having a semiconductor substrate could have that substrate made by any lithography process used in the manufacture of semiconductors.

Peeters, in column 9 lines 45-46, teaches nanoelectrode arrays detected by a resonance approach. Referring to claim 11, it would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body and having a nanoelectrode array could have that array constructed as a resonance device. If a nanoelectrode array can be incorporated into a nanodevice circulating or stationed in the body then it follows the device can be provided with any passive or active function within the capabilities of nanoelectrodes.

Peeters, in column 4 lines 41-45, teaches nanoelectrode arrays with substrates comprised of silicon, germanium, gallium arsenide, or other semiconductors. Referring to claim 14, it would have been obvious to one having ordinary skill in the art at the time the invention was made that a nanodevice or microdevice in the body and having a nanoelectrode array could have that array comprised of any of the common semiconductor materials.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkle in view of Ehnholm et al. US Patent No. 5882304. Merkle teaches a nanodevice circulating or stationed in the body but does not teach detection of that device with magnetic resonance. Ehnholm et al. teaches in column 4, lines 42-56, the use of ESR for tracking a probe in an object by measuring the ESR frequency of a sample in the probe. In column 1, lines 40-50, Ehnholm et al. teaches NMR for localizing contrasty markers in an instrument inside the body. It would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body and having a nanoelectrode array could have that array respond to ESR detection by providing the nanodevice with any desired level of magnetic susceptibility by incorporating any of the well-known paramagnetic substances recited in claim 13, and respond to NMR detection by incorporating elements having odd nuclear spin.

9. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkle in view of Schechter et al. US Patent No. 4120649. Merkle teaches a nanodevice circulating or stationed in the body but does not teach treatment of the circulating or stationary device to prevent immunologic response and prolong retention. Schechter et al. teaches the treatment of transplants with a compound to reduce antigenicity and prolong retention by the host.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body, having a nanoelectrode array, should and could have that device treated with any compound, such as ethylene glycol, which is known to reduce immune system response and increase retention.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merkle in view of Dustin et al. Patent No. 5071964. Merkle teaches a nanodevices circulating in the body but does not teach addition of a lipid anchor, using an organo hydroxyl, to the circulating device to facilitate its attachment to cell membranes. Dustin et al., e.g., in the *Abstract*, teach the use of lipid anchors to enable the attachment of circulating micelles to a variety of target molecules on a cell. Further, organo hydroxyls (e.g. ethylene glycol) are commonly used as cross-linking molecules that can be modified to have little effect on the chemistry of the molecules being linked. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention was made that a nanodevice or microdevice in the body, having a nanoelectrode array, could have that device provided with a lipid anchor if the device is to have any capability of interacting with cells.

Conclusion


11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Jung et al. US Patent No. 6,074,650 discusses in detail the use of the cross-linking molecules and membrane anchors.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Pass whose telephone number is 305-0726. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8382 for regular communications and (703) 746-8382 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0873.

Barry Pass 
April 12, 2002


Marvin M. Lateef
Supervisory Patent Examiner
Group 3700